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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

David T. Frederick, et al.

Art Unit: 3651

Serial No.: 09/086,857

Patent Examiner

Filed: May 29, 1998

Michael E. Butler

For: **System For Tracking And
Dispensing Medical Items
From Environmentally
Controlled Storage Area**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. § 1.131

R. Michael McGrady hereby declares as follows:

1. I am an Applicant of the Patent Application identified above and am the sole inventor of the subject matter described and claimed in claims 24 and 45 thereof.
2. I have personal knowledge of all matters set forth in this Declaration.
3. At all times mentioned herein I have been an employee of Diebold, Incorporated, the Assignee of the invention claimed in the Patent Application identified above, or its predecessor entity, MedSelect Systems, Inc. which has now merged into Diebold, Incorporated.
4. Prior to August 2, 1994 I had completed my invention as described and claimed in the subject Application in claims 24 and 45, in this country as evidenced by the following:


- a. Prior to August 2, 1994 having conceived of the idea of a system and method for providing medical items, I produced the Functional Specification (Software) document, the pertinent portions of which are attached hereto as Exhibit A.
- b. Prior to August 2, 1994 at the facilities of MedSelect Systems, Inc. located in Cranberry Township, Pennsylvania (now Diebold, Incorporated, the assignee of the subject Application) I assembled a system for dispensing medical items as described in Exhibit A and successfully tested its operation. The system included a computer with an associated data store which held data corresponding to a plurality of authorized users, a plurality of medical items and a plurality of storage locations in which medical items were stored. The system further included a user interface which included a display terminal with input devices including a card reader and "buttons" on a touch screen. The system further included a housing structure with an interior area having access thereto controlled by a door, and with a storage location for holding a plurality of medical items within the housing structure. The system further included a lock assembly on the housing structure, the lock being operatively connected to the computer such that the computer controlled the lock to change the lock between the locked and unlocked conditions, the door being prevented from opening when the lock was in the locked condition. The computer in the system was programmed and the system operated successfully such that when a user input identification data through the input devices which

corresponded to data for an authorized user stored in the data store, the computer operated to allow the user to input data corresponding to a medical item through an input device. The computer then operated to generate signals which changed the lock from the locked to the unlocked condition. This enabled the user to open the door of the housing structure to access the medical items in the interior area of the housing. The makeup of the system and the method of operation thereof being described in Exhibit A hereto.

5. As can be seen from Exhibit A, the invention as claimed in each of claims 24 and 45 was completed by being conceived and reduced to practice in this country prior to August 2, 1994. Each of the dates deleted from Exhibit A is prior to August 2, 1994.

6. The invention which is described and claimed in the above-identified Application, was not in public use or on sale more than one year before December 16, 1994, the filing date of Patent Application Serial No. 08/367,783 from which the above-identified Application claims priority pursuant to 35 U.S.C. § 120.

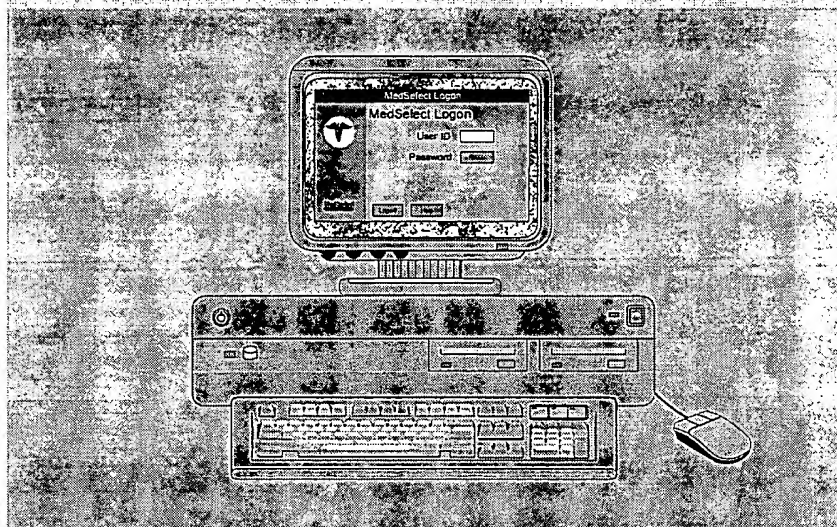
7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information are believed to be true, and further that such statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.


R. Michael McGrady

5-9-00
Date

Selectrac

Functional Specification (Software)



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System Functional Specification

1.1 Introduction

The System Functional Specification defines as completely as possible the specific tasks that the SelecTrac-CL and SelecTrac-Rx systems perform. It is the blueprint that is used to program the systems and to verify that the systems satisfy the criteria used to define them.

SelecTrac-CL and SelecTrac-Rx are both designed to store, count, and dispense supplies (such as catheters, guides, sheaths, etc.) and medications (such as syringes, vials, ampoules, packaged solids, etc.).

Chapter 1.2 explains the general functions of the SelecTrac systems.

1.2 System Function Overview

The SelecTrac Systems can be used separately or in conjunction with each other. This is accomplished in the logical database design which allows the products to share a common physical database structure.

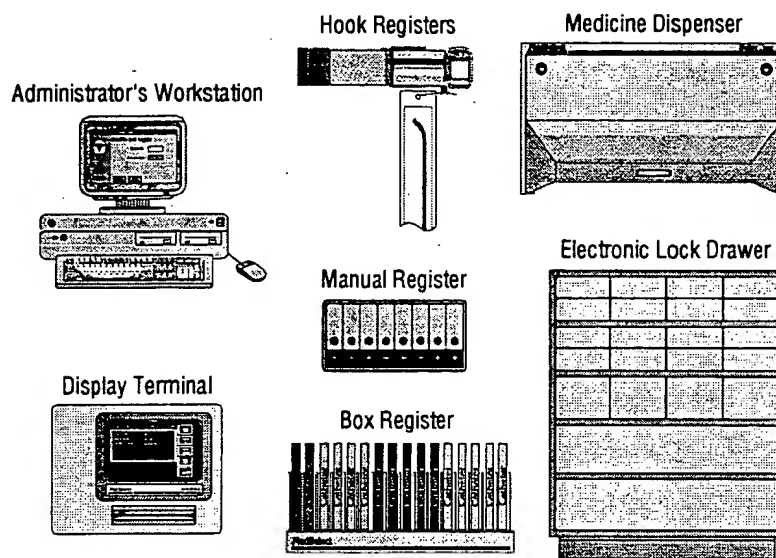


Figure 1.2-1. The SelecTrac System

The SelecTrac-CL system monitors the storage and utilization of supplies for Cardiac Labs. It tracks this inventory by using intelligent hooks, box registers, manual registers and manual data entry.

The SelecTrac-Rx system monitors the storage and utilization of medicines and controls the dispensing of these medicines for Nursing Stations and other hospital areas. It uses medicine dispensers (vials and solids), electronic lock cabinets (ELCs), and manual data entry to provide this functionality. A network link to the Hospital Information System (HIS) delivers orders from the pharmacy to the nursing station.

Both systems provide data forms for user data entry and reporting. They also have internal diagnostic capability. See Appendix 1 for a definition of each component of the SelecTrac Systems.

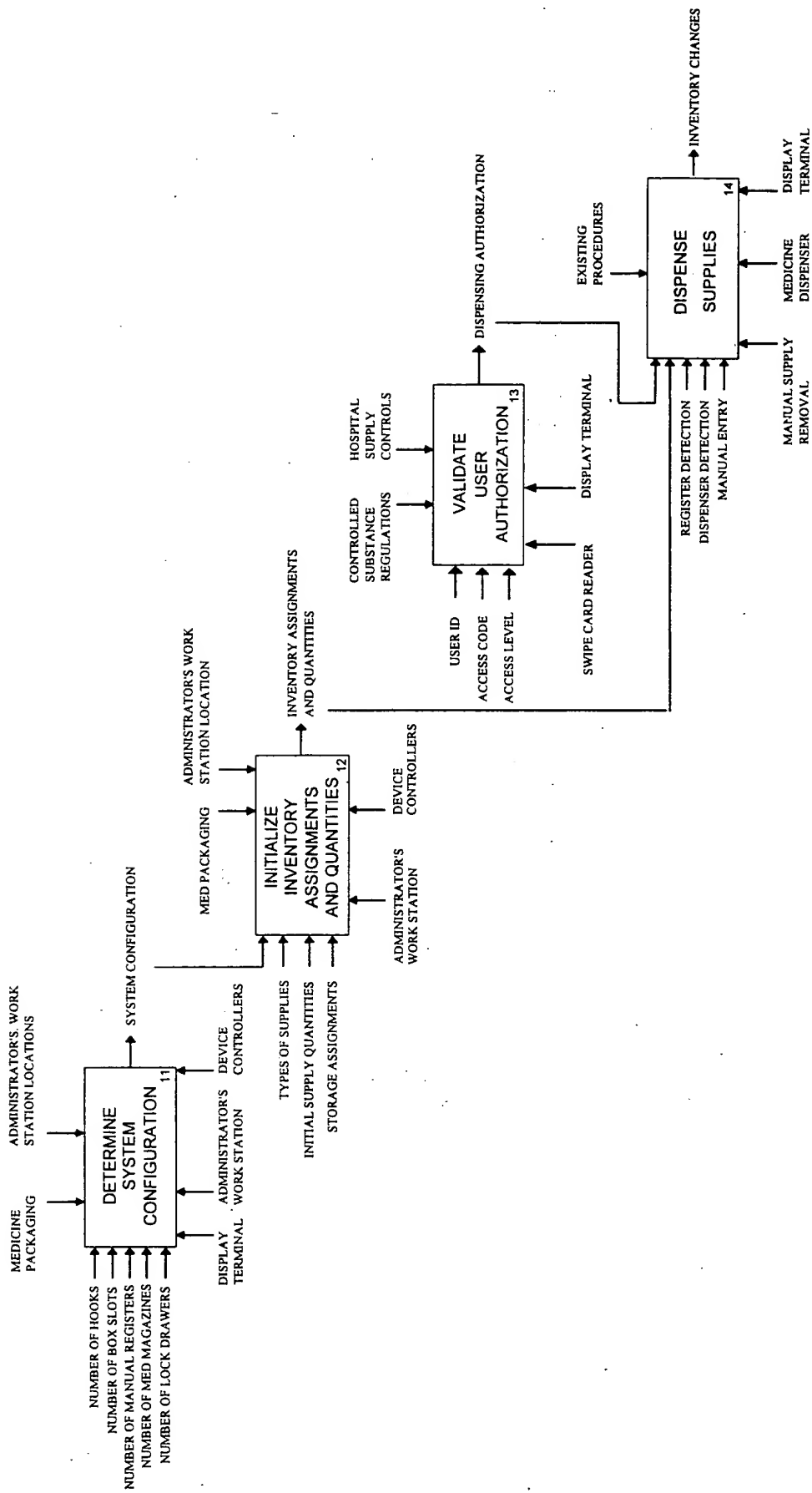


Figure 1.3-3. Monitor Working Inventory

Node A1

Node A1: Monitor Working Inventory

Figure 1.3-3 shows how the SelecTrac Systems monitor the working inventory.

Process 11: Determine System Configuration

The number and physical location of hook registers, box registers, manual registers for SelecTrac-CL systems and medicine dispenser magazines, and electronic lock cabinets (ELCs) for SelecTrac-Rx systems must be manually entered at the Administrator's Workstation (AWS) when the system is installed.

Non-system storage may also be manually configured and maintained within the SelecTrac system. An artificial controller address and position will be created by the system.

Process 12: Initial Inventory Quantities/Assignments

A list of all supplies to be controlled may be selected from a master supply list or manually entered at the AWS.

When more than one storage position is assigned the same supply, these positions may be treated as a position group for minimum quantity calculations.

The type of supply and initial quantity assigned to each register, medicine dispenser magazine, and electronic lock cabinet must be entered manually at the AWS.

Process 13: Validate User Authorization

Some supplies may require controlled access because of Government Regulations (as in the handling of narcotics) or the hospital's desire to control expensive supplies. These supplies must be kept in an ELC or medicine dispenser. Access to these supplies will be granted only after a valid user ID and personal identification number (PIN) are provided to the system at a display terminal. A swipe card for automatic entry of an identified user will be provided but the PIN must be entered manually. Any supply or medicine can require a second user ID and PIN. The user should logout when done dispensing, but the system will automatically logout the user if there is no activity for 1 minute, as a security precaution.

For SelecTrac-CL, a user will logon by using a swipecard or a touch screen keypad, but a PIN will not be required. This will record the user's name with activities as long as the user has not logged out. There will not be an automatic logout.

Process 14: Dispense Supplies

Supplies are dispensed manually at the hook and box registers, but the system automatically senses the change in inventory. Note that the system also automatically detects returns and restocking.

Supplies are also dispensed at the manual register, but the person adding or removing the supply must indicate the change in inventory by pushing a button once for each supply.

Supplies dispensed by a Medicine Dispenser are automatically updated by the SelecTrac systems. In the event that the SelecTrac system believes a medicine was dispensed, but the medicine was not actually dispensed, the user must manually inform the system at a display terminal. The system will then inquire if the user wants the medication dispensed from another magazine, if possible. It will also indicate which magazine failed in the error log.

The SelecTrac system will unlock an ELC drawer with proper authorization, but the user must indicate the quantity of supplies taken, returned, or stocked at the display terminal.

DATA INTEGRITY

The SelecTrac Systems minimize the requirements for data entry. Instead of requiring many fields, the SelecTrac systems allow the customer to leave them empty. However, some functionality may not be available when the data doesn't exist. For example, Minimum, Maximum, and Par Quantities are not required, but a Below Par report has no usefulness without this data. Since this may be acceptable to customers, the SelecTrac Systems do not make these fields mandatory.

To prevent data loss in the event of a hard disk failure and to keep enough free disk space for the Selectrac Systems to run efficiently, data is periodically archived to tape. The archive will be run on the first day of each month.

The customer can choose an archive period specified in months. For all patient charts that have been closed for the the archive period prior to the first day of the month, the charts and their associated procedures, medication orders, and inventory events will be saved to magnetic tape and deleted from the hard disk.

1.6 Graphical User Interfaces ---

There are two types of user interface stations in the SelecTrac Systems:

1. Administrator's Workstation with Keyboard and Mouse
2. Display Terminal with Touch Screen

The Administrator's Workstation (AWS). This workstation is a PC running Paradox for Windows. The AWS is where Patient Information is entered and reports are created. The AWS is also where supplies are assigned to storage locations and user profiles are created and maintained. A SelecTrac system may have more than one Administrator's Workstation.

The Display Terminal. The Display Terminal provides a "Touch Screen" graphical user interface. Display Terminals will be placed strategically to provide information at the time and place where it is needed most. This interface design supports both the SelecTrac-CL and SelecTrac-Rx products and attempts to make the "look and feel" as similar as possible.

Table 1.6-1 shows the forms on the SelecTrac-CL and SelecTrac-Rx systems.

SelecTrac-CL	SelecTrac-Rx
Logon	Logon
Patient Browser	Patient Browser
Patient Info	Patient Profile
Physician Card	Medication Order
Patient Usage	Patient Usage
	Supply Browser
	Supply Information

SELECTRAC-Rx TOUCH SCREEN:

The first form encountered by a user is the Logon form (Figure 1.6-3). The Logon form has a keypad graphic that may be used to enter a User ID Number. This number could also be automatically read into the system by a magnetic card reader or bar code reader that are options supported by SelecTrac. The current magnetic card reader only reads track 2 which can only be the numbers 0 through 9, the question mark (?) as a string start character, the equals sign (=) as a field separator and the semicolon (;) as the end of string character. When the Logon form is displayed for more than 30 seconds, a screen saver program is activated. Touching the screen will bring up the Logon form again.

After the User ID Number has been entered, the user is prompted to enter a Personal Identification Number (PIN) using the graphical keypad. After the PIN has been entered, the Logon form validates the User ID Number and PIN combination against the user's profile on the Database Server. If the combination is invalid, a message indicating that the Logon has failed appears, and the Logon form is again presented to allow the next Logon attempt. If the combination is valid, the Patient Browser form is activated. The SelecTrac-Rx Logon times out after the hospital specified timeout period (for instance, 1 minute) of inactivity as a security measure.

Room	Bed	Sex	Patient Name	Patient ID
1011	1	M	Johnson, Peter	14-2031
1011	2	M	Carr, Robert	14-2040
1012	1	F	Murray, Lisa	14-2100
1012	2	F	Coventry, Sarah	14-2130
1016	2	M	Pelletier, Lawrence	14-2132
1016	3	M	Schafer, James	14-2400
1017	1	F	Scott, Anna	14-2435
1017	3	F	Walker, Michael	14-2455

Buttons: Select, Patient Info, Help, Usage, Logout

Figure 1.6-8. *SelecTrac-Rx Patient Browser*

While the Patient Browser forms are similar for the SelecTrac-CL and SelecTrac-Rx systems, they are not identical.

The SelecTrac-Rx Patient Browser form (see **Figure 1.6-8**) displays patients assigned to each nursing station. The Patient Browser is a multiple page form to allow for any number of patients to simultaneously be in the system. Ten patients can be displayed on a single page with each patient on one line of the form with the following information and positions:

Column 1- 4	Room Number
Column 6- 8	Bed Number
Column 10-15	Sex

The Patient Profile form is a single page form that displays the following:

Patient Name: Doe, John A	Patient ID Number: 9263546
Gender: Male	Med Record Number: 003546
Age: 52	Date Admitted: 2/3/94
Height: 190.23 cm	Time Admitted: 13:00
Weight: 50.1 kg	Room #: 476
Birthdate: 01/05/40	Bed #: 2
Allergies: penicillin	
Referral Physician: Dr. Smith	

Figure 1.6-6. *SelecTrac-CL Patient Profile*

There is 1 graphical button on the SelecTrac-Rx Patient Profile form, starting in column 60. Touching this button has the following effect:

1. FINISH Returns to the Patient Browser form.

The Physician Card form displays supplies that are generally used by a physician for a particular type of procedure. The Physician Card form is a multiple page form to allow for any number of supplies to simultaneously be displayed.

Physician Name		Music Preference
Procedure Name		
Item	Supply Name	Manufacturer
		<input type="button" value="Up"/> <input type="button" value="Down"/>
		<input type="button" value="Finish"/>

Figure 1.6-7. *SelecTrac-CL Physician Card*

Ten supplies can be displayed on a single page with each supply on one line of the form with the following information and positions:

Column 1- 4	Item Number (A sequential number assigned for reference)
Column 6- 13	Status
Column 15-52	Supply / Manufacturer
Column 54-59	Number
Column 60-80	Buttons

Column 17-46	Patient Name
Column 48-59	Patient ID
Column 60-80	Buttons

The SelecTrac-Rx Patient Browser form displays these patients sorted 1st by room, then by bed. Touching anywhere on the line that displays a patient's name and ID number indicates that this is the patient the user is referring to. Button actions will apply to this patient.

There are 7 graphical buttons on the SelecTrac-Rx Patient Browser form, starting in column 60. Touching each button has the following effect:

- | | |
|-----------------|-------------------------------------------------------------------------------------------------------|
| 1. SELECT | Supplies are automatically assigned to the selected patient and the Supply Browser form is activated. |
| 2. PATIENT INFO | Displays the profile for this patient |
| 3. UP ARROW | Returns to the previous page of patients |
| 4. DOWN ARROW | Advances to the next page of patients |
| 5. HELP | Provides online instructions about using the current form |
| 6. USAGE | Displays the supplies that have been charged to a patient |
| 7. LOGOUT | Logs out and Returns to the Logon screen |

The Patient Profile form displays the following patient information:

Patient Name: Doe, John A	Patient ID Number: 9263546
Gender: Male	Med Record Number: 003548
Age: 52	Date Admitted: 2/3/94
Height: 190.23 cm	Time Admitted: 13:00
Weight: 50.1 kg	Room #: 476
Birthdate: 01/05/40	Bed #: 2
Allergies: penicillin	
Referral Physician: Dr. Smith	
	<input type="button" value="Orders"/>
	<input type="button" value="Finish"/>

Figure 1.6-9. SelecTrac-Rx Patient Profile

There are 2 graphical buttons on the SelecTrac-Rx Patient Profile form, starting in column 60. Touching each button has the following effect:

- | | |
|-----------|--------------------------------------|
| 1. ORDERS | Activates the Medication Orders form |
| 2. FINISH | Returns to the Patient Browser form. |

The Medication Order form is activated by the ORDERS button on the Patient Profile Form. The Medications Order form is a multiple page form to allow for any number of med orders to simultaneously be displayed for a patient. Five med orders sorted with the PRNs listed last can be displayed on a single page. Each supply on one line of the form will display the following information and positions:

Line 1 Column 1-20	Trade Name
Line 2 Column 1-20	Generic Name
Line 1 Column 22-26	Order Number (Assigned by pharmacy system)
Line 2 Column 22-26	Order Quantity
Line 1 Column 28-36	Dose/Units
Line 2 Column 28-36	Unit Dose/Units
Line 1 Column 38-44	Route
Line 2 Column 38-44	Freq
Line 1 Column 46-59	Start Date/Time
Line 2 Column 46-59	End Date/Time

Patient Name: Doe, John A.		Patient ID: 9263548				Dispense
Trade Name	Order	Dose	Route	Start		
Generic Name	Qty	Unit Dose	Freq	End		
Zestril	7322	350mg	ord	6/6/04 14:00		Med Info
Lisinopril	1	350mg	QD	6/6/04 11:00		
Dilantin	7325	100mg	ord	6/6/04 15:00		
Phenytoin	2	50mg	BID	6/7/04 12:00		
Darvocet	7330	65/650	ord	6/6/04 15:00		Help
Wygesic	1	65mg	PRN	6/6/04 16:00		Finish

Figure 1.6-10. SelecTrac-Rx Medication Order Form

The Medication Order form has three graphical buttons, starting in column 60. Touching each button has the following effect:

- 1. DISPENSE** A unit dose of the selected supply is dispensed or an Electronic Lock Cabinet drawer is opened. If the supply is in an electronic lock cabinet, the user is prompted to enter the quantity taken on a graphical keypad. If this supply requires a witness before dispensing (2nd PIN required flag), the Logon form will be displayed so that a 2nd user may logon as a witness. After the witness is verified, dispensing proceeds. If the hospital wants the remaining count verified (ELC count required flag), then the user will be prompted to enter the count remaining in the opened drawer. In either case, the supplies are automatically assigned to the selected patient.
- 2. MED INFO** Displays the Medication Order for this supply (see **Figure 1.6-11**)
- 3. UP ARROW** Returns to the previous page of medication orders
- 4. DOWN ARROW** Advances to the next page of medication orders
- 5. HELP** Provides online instructions about using the current form
- 6. FINISH** Returns to the Patient Browser form.

The Supply Browser form is a multiple page form to allow for any number of supplies and medicines to simultaneously be in the system. The Supply Browser is not accessible at hospitals that choose the "med order only" option in the hospital configuration table.

Brand Name	Generic Name	Strength	Form
Demoral	meperidine	50mg	tablet
Demoral	meperidine	75mg	tablet
Sublimaze	fentanyl	2 ml x 1	ampoule
Sublimaze	fentanyl	5ml	ampoule
Sublimaze	fentanyl	30 ml	ampoule
Versed	midazolam	2mg/2ml	vial
Versed	midazolam	10mg/2ml	vial
	duramorph	5mg/10ml	ampoule

Figure 1.6-11. *SelectTrac-Rx Supply Browser*

Ten supplies can be displayed on a single page with each supply on one line of the form with the following information and positions:

Column 1-20	Supply Name
Column 22-41	Generic Name
Column 43-51	Strength
Column 53-59	Form
Column 60-80	Buttons

There are 7 graphical buttons on the SelectTrac-Rx Supply Browser form, starting in column 60. Touching each button has the following effect:

1. DISPENSE A unit dose of the selected supply is dispensed or an Electronic Lock Cabinet drawer is opened. If the supply is in an electronic lock cabinet, the user is prompted to enter the quantity taken on a graphical keypad. If this supply requires a witness before dispensing (2nd PIN required flag), the Logon form will be displayed so that a 2nd user may logon as a witness. After the witness is verified, dispensing proceeds. If the hospital wants the remaining count verified (ELC count required flag), then the user will be prompted to enter the count remaining in the opened drawer. In either case, the supplies are automatically assigned to the selected patient.
2. MED INFO Displays the Medication Order for this supply (see **Figure 1.6-11**)
3. UP ARROW Returns to the previous page of patients
4. DOWN ARROW Advances to the next page of patients
5. RESTOCK Activates the inventory mode for restocking supplies
6. HELP Provides online instructions about using the current form
7. FINISH Returns to the Patient Browser form

1.9 Systems Communications

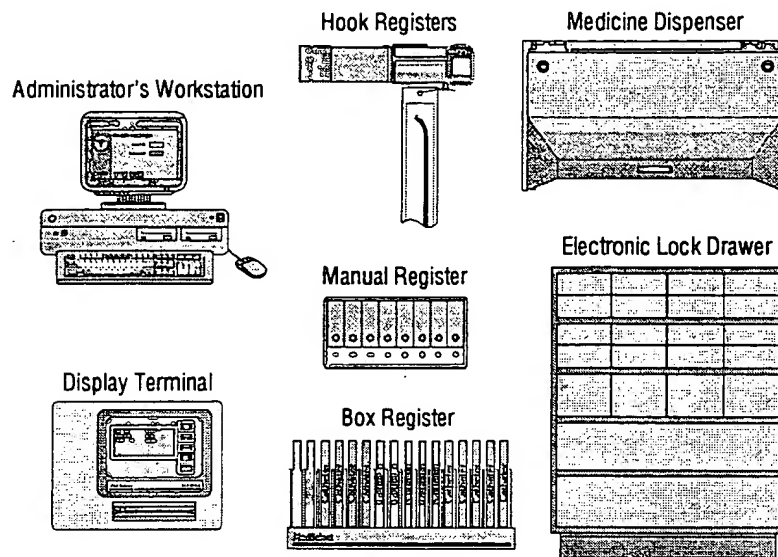


Figure 1.9-1. *The SelectTrac System*

- **Hooks to hook controllers:** The microprocessors in each Hook Register are wired in series on a ribbon cable. They are polled (asked for data) periodically by the hook controller. The polling software was developed by MedSelect. The hook microprocessors respond to the hook controller with the accumulated inventory changes at each microprocessor since the last time the controller polled it. Each hook controller can communicate with 16 hooks. Multiple hook controllers are wired in series with flat cable and RJ45 plug connectors.
- **Hook Controllers to Display Terminals:** Hook controllers communicate with display terminals through a MedSelect proprietary interface board called the IBPC (Inventory Bus Protocol Converter). The IBPC resides inside the display terminal and is connected to the display terminal's bus with a ribbon bus cable. The hook controllers are wired in parallel with a single connection directly onto the IBPC in the display terminal. It is a 4-wire connection, where 2 wires (send and receive) provide communications and two wires (live and ground) provide power to the hook controllers. Each display terminal has an IBPC connected to serial communication port 1 (COM1:) by a ribbon cable. In addition to protocol conversion, the IBPC provides error and collision detection on the inventory bus.
- **Box Registers to Display Terminals:** Box registers are wired in parallel by ribbon cable with a single connection directly onto the IBPC in the Display Terminal. Like the hook controller connection, a 4-wire connection provides communications and power to the Box Registers.

- **Manual Registers to Display Terminals:** Communicate the same way as box registers. Box registers and manual registers can be wired in parallel on the same line going to the display terminal.
- **Dispensers with Display Terminals:** Also communicate through the IBPC.
- **Display Terminals with Database Server:** Display terminals communicate with the database server via 10-base-T ethernet (RG58 thinwire, AUX thickwire & token ring are also supported). Ethernet provides the capability to have virtually unlimited numbers of display terminals communicating with the database server. Each display terminal will have a 3COM ethernet controller which is connected to the display terminal's bus by a ribbon bus cable. The ethernet board then connects to the ethernet by a 10-base-T cable to a multi-port communication hub. The communications software is LanTastic/AI by Artisoft (TCP/IP, Novell and other protocols are also supported).
- **Administrator Workstations with Database Server:** The Administrator's Workstations communicate with the Database Server using ethernet and LanTastic/AI (and other supported networks). The database is read and written to using Borland's Paradox for Windows (Run-time) software and MedSelect client-server software.
- **Admission-Discharge-Transfer (ADT) System Interface:** This interface is not yet defined and may be hospital specific. Patient admission information will be provided to the MedTrac Systems from the ADT.
- **Hospital Information System (HIS) System Interface:** This interface is not yet defined and may be hospital specific. Patient/Procedure information will be sent to the HIS when the procedure is closed.
- **MedSelect Diagnostic Interface:** This interface allows MedSelect engineers to access a customer's system remotely. This is accomplished by using internal 14.4 Kbaud modems on an analog telephone line. The software used is Symantec's PC-AnyWhere for Windows which allows a MedSelect engineer to connect to the Administrator's Workstation to diagnose problems.